K092806

510(k) Summary

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Taiwan
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OCT - 9 2009

Date Prepared: August 31, 2009

Name of Device

Arm Blood Pressure Monitor Model KP-7770

Name/Address of Sponsor

K-jump Health Co., Ltd.
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park
Taipei Hsien
Taiwan
Phone: + 886 2 22991378
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Contact Person: Jason Cheng

Common or Usual Name

Arm Blood Pressure Monitor

Classification Name

Class II § 870.1130; System, Measurement, Blood Pressure, Non-Invasive

Predicate Device

K-jump Health Co., Ltd.'s Arm Blood Pressure Monitor Smartlogic Model KP-7500 and Fuzzylogic Model KP-7500D, K083753.

Intended Use/Indications for Use

The device is intended to measure the systolic and diastolic blood pressure and pulse rate (heart rate) by using an inflating cuff wrapped around the arm. The device is indicated for use with adults.

The device displays irregular pulse detection (IPD) icon on LCD screen when irregular pulse is detected during blood pressure measurement.

Technological Characteristics

The device is an electronic blood pressure monitor. The device consists of an inflating cuff, a LCD display, a bellows sensor, an internal air pump, a leakage valve, an exhaust valve, a battery power resource, and keys for operation.

Performance Data

The Arm Blood Pressure Monitor Model KP-7770 complies with the following FDA-recognized consensus standards, to the extent that these standards are applicable to this device:

- AAMI/ANSI SP10 (2002 / A1:2003);
- IEC 60601-1 (1988); and
- IEC 60601-1-2 (2002).

The KP-7770 also complies with the following additional standards:

- EN61000-4-2 (1995); and
- EN61000-4-3 (2002).

Clinical performance of the modified device is remain unchanged; therefore another clinical trial for this device, KP-7770, is not required.

Substantial Equivalence

The KP-7770 has the same intended use and indications for use as K-Jump's Arm Blood Pressure Monitor Model KP-7500 and KP-7500D.

The KP-7770 has the same technological characteristics as the KP-7500 except that the KP-7770 can use MOMI or fuzzy logic method to measure blood pressure rather than the KP-7500 which can only use smart logic method or the KP-7500D which can only use fuzzy logic method.

Thus, the minor differences between the KP-7770 and the predicate devices are not new technological characteristics for arm blood pressure monitors. Therefore, these minor technological differences do not raise any new questions of safety or effectiveness. Accordingly, the KP-7770 is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

K-jump Health Co., Ltd.
c/o Mr. Jason Cheng
Assistant Manager, Product Planning Department
No. 56 Wu Kung 5th Road, Wu Ku Industrial Park
Taipei Hsien 248
TAIWAN

OCT - 9 2009

Re: K092806
Trade/Device Name: Auto Digital Upper Arm Blood Pressure Monitor, Model KP-7770
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: September 9, 2009
Received: September 11, 2009

Dear Mr. Cheng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. J. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if Known): K092806

Device Name: Arm Blood Pressure Monitor Model KP-7770

Indication for Use:

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The devices display irregular pulse detection (IPD) icon on LCD screen when irregular pulse is detected during blood pressure measurement.

Prescription Use _____ (Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use X (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092806